UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,472	04/08/2004	Giorgio Di Palma	ANGIO P-43/ 500622.20052	1059

7590 01/11/2006

EXAMINER	
AHMED, AAMER S	

ART UNIT	PAPER NUMBER
3763	

Harry K. Ahn, Esq.
Reed Smith LLP
599 Lexington Avenue
New York, NY 10022

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,472	PALMA, GIORGIO DI	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-14, 16-19 and 21- 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldenberg ('198). Furthermore Claims 1, 2, 4, 5, 11, 12, 16- 19, 21, 22 and 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldenberg and Chu et al. ('577).

As to Claim 1 Goldenberg et al and Chu et al describe catheter devices having an anchoring end, comprising: a shaft having a proximal portion and a distal portion; a hub attached to the proximal portion of the shaft, the hub having a first member (Goldenberg 42), a second member (Goldberg 50) slidably coupled to the first member, and a latch (Goldenberg 52); and a cord (Goldenberg 46) running from the distal portion of the shaft through the shaft and having a

free end exiting from the hub; the hub having an unlatched state that allows pulling of the cord such that the distal portion of the shaft forms an anchoring shape, and a latched state in which the latch latches the first and second members together when the second member slidably moves relative to the first member so as to secure the cord to the hub. (See Goldenberg Figures 1 and 1A and Chu Figure 2).

Moreover, as to Claim 2, Goldenberg et al and Chu et al disclose a manually operable release member coupled to the latch and being manually operable to release the latch from the latched state, wherein: a sliding movement of the second member relative to the first member causes the latch to switch from the unlatched state to the latched state; manual operation of the release member together with a reverse sliding movement causing the latch to switch from the latched state to the unlatched state, wherein unlatching of the latch is disabled without first operating the release member. (See Goldenberg Figures 1 and 1A and Chu Figures 6 and 7).

Furthermore, as to Claim 3, Goldenberg et al discloses that the latch produces a tactile feedback when the first and second members are latched.

In Addition, as to Claim 4, Goldenberg et al and Chu et al each describes that one of the first and second members has a tongue (Goldenberg 52); and the other of the first and second members has a recess that receives the tongue such that when the first and second members are latched, the cord is frictionally secured between the tongue and the recess. (See Goldenberg Figures 1 and 1A and Chu Figure 6).

Also as to Claim 5, Goldenberg et al and Chu et al each teaches that the latch, as mentioned above regarding claim 1, comprises: a recess disposed on the first member; a projection disposed on the second member (Goldenberg 52) and adapted to be received in the

recess to latch the first and second members together. (See Goldenberg Figure 1 and Chu Figure 6).

Moreover, as to Claim 7 Goldenberg et al discloses that the latch described above in regards to claim 5, further comprises a release member coupled to the projection (50) and operable to release the projection from the recess. (See Figure 1A).

In addition, as to Claim 8 Goldenberg et al teaches that the catheter device as mentioned above in regards to Claim 7, further comprises of a strain relief (28) slidably coupled to the shaft and adapted to cover the release member to limit the ability of a person to release the latch. (See Figure 1).

In addition, as to Claim 9, Goldenberg et al teaches that the catheter device mentioned above in regards to Claim 5 comprises a strain relief (28) slidably coupled to the shaft and adapted to cover the projection so as to bias the projection into the recess. (See Figure 1).

Furthermore, as to Claim 10 Goldenberg et al describes a strain relief (28) slidably coupled to the shaft and adapted to at least partially cover the hub and at least partially cover the proximal portion of the shaft. (See Figure 1).

In Addition, as to Claim 11 Goldenberg et al and Chu et al each teaches an anti-rotation longitudinal slot disposed on one of the first and second members; an anti-rotation slide protrusion (Goldenberg 52) disposed on the other of the first and second members, and sized to be received in and to move along the anti-rotation longitudinal slot. (See Goldenberg Figure 1 and Chu Figure 6)

Moreover, as to Claim 12 Goldenberg et al and Chu et al each discloses a recess disposed on one of the first and second members; a projection (Goldenberg 52) disposed on the other of the first and second members. (See Goldenberg Figure 1 and Chu figure 6).

Also, as to Claim 13 Goldenberg et al describes that the hub further comprises: a port (40) in communication with a lumen of the hub, the cord passing through a deformable sealing material disposed in the port. (See Figure 1 and Column 2 Line 51).

In Addition, as to claim 14, Goldenberg et al teach that the catheter comprises of a deformable sealing material including a deformable semi-liquid material. (See Column 3 line 32).

Furthermore, as to claim 16 Goldenberg et al and Chu et al each discloses, a catheter device having an anchoring end, comprising a shaft having a proximal portion and a distal portion; a hub attached to the proximal portion of the shaft, the hub having a latch; a cord running from the distal portion of the shaft through the shaft and having a free end exiting from the hub; a slide member slidably coupled to the hub, the slide member having an unlatched state that allows pulling of the cord such that the distal portion of the shaft forms an anchoring shape, and a latched state in which the hub and the slide member are latched together by the latch, the latch latching the hub and the slide member when the slide member slidably moves toward the hub. (See Goldenberg Figures 1 and 1A and Chu Figure 2).

Also, as to Claim 17 Goldenberg et al and Chu et al each discloses a catheter device comprising a manually operable release member coupled to the latch and being manually operable to release the latch from the latched state, wherein: a sliding movement of the slide member relative to the hub causes the latch to switch from the unlatched state to the latched

state; manual operation of the release member together with a reverse sliding movement causing the latch to switch from the latched state to the unlatched state, wherein unlatching of the latch is disabled without first operating the release member. (See Goldenberg Figures 1 and 1A and Chu Figure 2).

Moreover, as to Claim 18 Goldenberg et al and Chu et al each disclose a catheter device wherein: one of the hub and the slide member has a tongue; and the other of the hub and the slide member has a recess that receives the tongue such that when the first and second members are latched, the cord is frictionally secured between the tongue and the recess. (See Goldenberg Figures 1 and 1A and Chu Figures 6 and 7).

Furthermore, as to Claim 19 Goldenberg et al and Chu et al each describes the catheter device wherein the latch comprises: a recess disposed on the hub and a projection disposed on the slide member. (See Goldenberg Figures 1 and 1A and Chu Figure 6).

Also, as to Claim 21 Goldenberg et al and Chu et al each teach the presence of an anti-rotation longitudinal slot disposed on one of the hub and the slide: member; an anti-rotation slide protrusion disposed on the other of the hub and the slide member, and sized to be received in and to move along the anti-rotation longitudinal slot to limit a rotational movement of the slide member relative to the hub. (See Goldenberg Figures 1 and 1A and Chu Figure 6).

Moreover, as to Claim 22 Goldenberg et al al and Chu et al each describe the catheter device, further comprising: a recess disposed on one of the hub and the slide member; a projection disposed on the other of the hub and the slide member and adapted to be received in the recess to prevent the slide member from sliding off the hub. (See Goldenberg Figures 1 and 1A and Chu Figure 6).

In addition, as to Claim 23 Goldenberg et al, describe the catheter wherein the hub further comprises: a port in communication with a lumen of the hub, the cord passing through a deformable sealing material disposed in the port. (See Figures 1 and 1A and Column 2 Line 51).

In Addition, as to claim 24, Goldenberg et al teach that the catheter comprises of a deformable sealing material including a deformable semi-liquid material. (See Column 3 line 32).

Also as to Claim 25 Goldenberg et al and Chu et al each discloses a manually operable release member coupled to the latch and being manually operable to release the latch from the latched state, a first predetermined movement of the second member relative to the first member causing the latch to switch from the unlatched state to the latched state; manual operation of the release member together with a reverse predetermined movement causing the latch to switch from the latched state to the unlatched state. (See Goldenberg Figures 1 and 1A and Chu Figure 6).

Furthermore, as to Claim 26 Goldenberg et al and Chu et al each describes the catheter device wherein: one of the first and second members has a tongue; and the other of the first and second members has a recess that receives the tongue such that when the first and second members are latched, the cord is frictionally secured between the tongue and the recess. (See Goldenberg Figures 1 and 1A and Chu Figure 6)

In addition, as to Claim 27 Goldenberg et al and Chu et al each describe the catheter wherein the latch comprises: a recess disposed on the first member; a projection disposed on the second member and adapted to be received in the recess to latch the first and second members together. (See Goldenberg Figures 1 and 1A and Chu Figure 6).

Moreover, as to Claim 28 Goldenberg et al and Chu et al each discloses the catheter device further comprising: an anti-rotation longitudinal slot disposed on one of the first and second members; an anti-rotation slide protrusion disposed on the other of the first and second members, and sized to be received in and to move along the anti-rotation longitudinal slot to limit a rotational movement of the second member relative to the first member. (See Goldenberg Figures 1 and 1A and Chu Figure 6).

Also, as to Claim 29 Goldenberg et al and Chu et al each discloses a method of anchoring and releasing a distal end of a catheter in a body cavity of a patient by a cord extending through the catheter and exiting from a hub, the method comprising: latching first and second hub pieces by a predetermined engagement movement between the first and second hub pieces to hold the cord against movement; unlatching the first hub piece from the second hub piece by a reverse movement of the first and second hub pieces; and manually operating a release member coupled to the hub to enable the step of unlatching, the step of unlatching being disabled without first operating the release member. (See Goldenberg Figures 1 and 1A and Chu Figures 2 and 6).

Furthermore, as to Claim 30 Goldenberg et al and Chu et al each discloses a method wherein: the step of latching is a sliding motion of the first hub piece relative to the second hub piece in a first axial direction of the hub; and the step of unlatching is a sliding' motion of the first hub piece relative to the second hub piece in an opposite axial direction from the first axial direction. (See Goldenberg Figures 1 and 1A and Chu Figures 2 and 6).

Finally, as to Claim 31 Goldenberg et al discloses a method, further comprising: providing a strain relief that at least partially covers the release member to limit the ability of a

person to release the latch; and removing the strain relief to expose the release member prior to the step of manually operating a release member. (See Figures 1 and 1A).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg ('198). Referring to claims 6 and 20, it would have been an obvious matter of design choice to provide the first member of the hub with a second recess and adapted to receive the projection disposed on the second member. Applicant has not disclosed that the specific inclusion of the second recess solves any stated problem that invention would perform equally well with one recess such as described in Claim 5 and 19 and taught by Goldenberg.

Furthermore Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg ('198). Referring to claim 15, it would have been an obvious matter of design choice to provide that the higher durometer material serve as the upper enclosure above the

lower durometer seal of deformable material. Applicant has not disclosed that the specific order of the materials solves any stated problem that the invention would perform equally well if the deformable material above the higher durometer enclosure as taught by Goldenberg.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Pat. No. 3,119,392	Zeiss et al.
U.S. Pat. No. 6,159,177	Amos et al.
U.S. Pat. No. 5,725,504	Collins
U.S. Pat. No. 6,716,207	Farnholtz
U.S. Pat. No. 6,702,780	Gilboa
U.S. Pat. No. 20030050	Hayzelden
U.S. Pat. No. 6,730,058	Hayzelden
U.S. Pat. No. 4,643,720	Lanciano
U.S. Pat. No. 6,454,740	Mody
U.S. Pat. No. 6,235,001	O'Holloran
U.S. Pat. No. 5,041,085	Osborne
U.S. Pat. No. 5,399,165	Paul
U.S. Pat. No. 5,730,724	Plishka
U.S. Pat. No. 20030216711	Rabiner
U.S. Pat. No. 6,579,279	Rabiner

U.S. Pat. No.	6,508,789	Sinnott
U.S. Pat. No.	20010049490	Slanda
U.S. Pat. No.	6,699,233	Slanda
U.S. Pat. No.	6,607,505	Thompson
U.S. Pat. No.	6,203,525	Whayne

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AA

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT
TECHNOLOGY CENTER